



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 15 2000

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The Honorable Michael Bilirakis
Chairman
Subcommittee on Health and Environment
Committee on Commerce
House of Representatives
Washington, D.C. 20515-6118

Dear Mr. Chairman:

Thank you for your letter of November 23, 1999, in which you comment on certain aspects of FDA's Notice of Proposed Rulemaking (NPRM) entitled, "Use of Ozone-Depleting Substances; Essential use Determinations," as published in the September 1, 1999, Federal Register. Specifically, you state that the NPRM errs as matter of law by indicating that the Clean Air Act or the Montreal Protocol requires an eventual end to any and all essential uses of chlorinated fluorocarbons (CFCs) within the United States.

Your letter has been forwarded to Docket No. 97N-0023 for inclusion in the record of comment on the proposed rule. Your comments will be considered as FDA moves forward in the rulemaking process.

Your continuing interest in this issue is appreciated.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

cc: The Honorable Sherrod Brown
Ranking Minority Member
Subcommittee on Health
and Environment
Committee on Commerce

97N-0023

-C 9630 /ANS

Congress of the United States

Washington, DC 20515

November 23, 1999

Dr. Jane E. Henney
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Henney:

As you know, I have taken an active interest in the implementation of Title VI of the Clean Air Act and proposals which would affect the granting or denial of essential use designations for chlorofluorocarbon ("CFC") based metered-dose inhalers (MDIs). In this regard, I feel compelled to note that the September 1, 1999 Federal Register Notice of Proposed Rulemaking regarding the Use of Ozone-Depleting Substances; Essential Use Determinations ("NPRM") (64 Fed.Reg 47719) in several places misstates applicable law regarding the granting or denial of essential use designations for CFC-based MDIs in the United States.

In specific, the NPRM states or implies in several instances that either the Clean Air Act ("CAA") or the Montreal Protocol ("Protocol") require the Parties to the Protocol to eventually prohibit all production or importation of CFCs for any use. While the NPRM does indicate that essential uses of CFCs now exist and will continue to exist for some indefinite period of time, subject to further notice and comment rulemaking, the NPRM errs as a matter of law when it indicates that the CAA or the Protocol require an "eventual" end to any and all essential uses of CFCs within the United States.

In specific, on page 47719 of the NPRM, in the Background Section, it is stated that, "the United States has agreed to eventually phase out all uses of CFC's." Additionally, on page 47734 of the NPRM, in response to comments received on the March 6, 1997 Advance Notice of Proposed Rulemaking ("ANPR"), it is stated that, "Congress later enacted provisions of the Clean Air Act that codified the decision to fully phase out the use of CFCs over time . . ." Finally, on page 47738 of the NPRM, in the Analysis of Impacts, it is stated that "the Parties to the Protocol have agreed to eventually eliminate all uses of ODS's [ozone depleting substances]," and further that, "Although the Clean Air Act and the Montreal Protocol require the eventual elimination of essential-use designations for these products, the agency has carefully structured its rule to avoid negative impacts on the nation's public health."

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All of these statements are either factually incorrect or subject to misinterpretation. First, the Clean Air Act Amendments of 1990 ("1990 Amendments," Public Law 101-549) provided for a phase-out of carbon tetrachloride and other class I substances. However, subsection 604(d) of the 1990 Amendments explicitly provided for exceptions for essential uses of methyl chloroform, medical devices and aviation safety. In specific, paragraph 604(d)(2) provides that "*Notwithstanding the termination of production* required by subsection (b), the Administrator, after notice and opportunity for public comment, shall, to the extent such action is consistent with the Montreal Protocol, authorize the production of limited quantities of class I substances solely for use in medical devices if such authorization is determined by the Commissioner, in consultation with the Administrator, to be necessary for use in medical devices." (Emphasis added).

Subsection 604(d) of the 1990 Amendments clearly indicates that continued production of CFCs for certain essential uses of class I substances is permissible, subject to a finding of necessity, consistency with the Montreal Protocol and an overall percentage limitation. Moreover, as opposed to other production and consumption exceptions contained within section 604 (e.g., fire suppression and explosion prevention under subsection 604(g)) and section 605 (affecting Class II substances) the provisions of subsection 604(d) are not limited in duration. Therefore, it is clear that the Clean Air Act does not explicitly provide for the "eventual" elimination of all essential-use designations.

The Food and Drug Administration has, in fact, acknowledged this interpretation of the law during testimony before Congress. Dr. John Jenkins, Director of the Division of Pulmonary Drug Products, Center for Drug Evaluation and Research testified before the Subcommittee on Health and Environment on May 6, 1998. In his written statement, Dr. Jenkins indicated that, "Title VI of the Clean Air Act and EPA's implementing regulations exempt medical products that FDA, in consultation with EPA, has determined to be essential." While Dr. Jenkins noted that the ANPR "set forth a potential process for FDA to review the essential use determinations of currently marketed CFC-MDIs," later in his testimony Dr. Jenkins also indicated that "it was not possible at this time to predict when [alternative non-CFC] products will be approved for marketing in the United States and whether the alternative products will adequately serve the needs of patients."

The NPRM, in fact, provides under "K. Determinations of Continued Essentiality" that "the public will have the opportunity to comment on the acceptability of alternatives before FDA removes the essential use designation for any particular active moiety." Clearly then, both the past interpretations of the law by FDA, in addition to the process for evaluating essential use exemptions outlined the NPRM, indicate that the decision on whether or not to remove an essential use exemption is not pre-ordained. Rather, it is a process by which the FDA will evaluate and balance certain criteria and solicit public comment on patient acceptance. It is a process which relies on certain facts which cannot be determine *a priori*.

The Montreal Protocol also does not contain a time limitation on the granting of essential uses. Article 2A of the Protocol provides that calculated levels of consumption for Group I of Annex A Substances (CFC-11, CFC-12, CFC-113, CFC-114 and CFC-115) shall not exceed zero after 1 January 1996 "save to the extent that the Parties decide to permit the level of production or consumption that is necessary to satisfy uses agreed by them to be essential." Decision IV/25, adopted by the Fourth Meeting of the Parties, indicates that use of a controlled substance should only qualify as essential if "(i) it is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and (ii) there are no available technical and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health." Thus, while essential use exemptions are subject to agreement by the Parties to the Protocol, they are not specifically limited as to duration.

There is additionally no indication within the existing Decisions of the Parties that granting a current essential use exemption carries with it a requirement for "eventual" elimination of each and every last use. Again, quoting from Dr. Jenkins May 6, 1998 testimony regarding the ANPR, "it is important again to emphasize that the Parties to the Montreal Protocol have not adopted the year 2005, or any other date, for ending essential-use exemptions for CFCs used in MDIs for the treatment of asthma and COPD."

The Environmental Protection Agency(EPA), which has authority to implement the Clean Air Act and provisions of the Montreal Protocol, has also indicated that there is no presumed or "eventual" end to certain essential use designations. In fact, the EPA has indicated that both stockpiled and newly produced CFCs remain available for essential uses for CFC-based MDIs.

In specific, in a April 22, 1998 letter to the Honorable John D. Dingell, Acting Assistant Administrator for Air and Radiation, Richard Wilson, indicated that, "while there is no obvious de minimis authority under either the Protocol or the Clean Air Act, the provisions that do offer flexibility for continuing production for essential uses remain in force until technically and economically feasible alternatives become available." Mr. Wilson specifically noted that the continuing use of stockpiled or recycled CFCs was permissible, stating that "CFCs stockpiled before the production phaseout in 1996 can continue to be used, for any use, including "de minimis" uses, until such stockpiles are depleted." Thus, under this interpretation of the CAA and the Protocol, essential uses could continue until stockpiles are depleted and beyond, presuming that technically and economically feasible alternatives were not available.

Nor does EPA consider that there is any current provision in the Protocol which presently "overrides" existing Decisions of the Parties regarding essential uses or existing CAA provisions that allow continuance of essential use designations for medical devices. In the April 22, 1998 letter noted above, EPA Acting Assistant Administrator Wilson indicated that section 614(b) of the CAA (allowing the more stringent provisions of the CAA or the Protocol to apply) would not

Dr. Jane E. Henney
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require an "eventual" or absolute end to the utilization of CFCs for MDIs. Mr. Wilson explicitly stated that, "under Section 614(b), the Montreal Protocol's essential use provision allowing production of CFCs for MDIs as long as technically and economically feasible alternatives are not available would mean that the U.S. would not be forced, under either the Clean Air Act or the Montreal Protocol, to phase out production of CFCs until the use of CFCs in MDIs is no longer essential by virtue of the availability of safe and effective alternatives."

In summation, I believe that FDA should take care to correctly indicate what is legally required and what is not legally required under the Montreal Protocol and the Clean Air Act. The present NPRM is flawed in certain statements of the law regarding the termination of any and all essential uses for medical devices. I would respectfully request that the FDA take these comments into consideration in the development of a final rule for essential use determinations regarding ozone depleting substances.

Sincerely,

A handwritten signature in black ink, reading "Michael Bilirakis". The signature is fluid and cursive, with the first name "Michael" and last name "Bilirakis" clearly legible.

Michael Bilirakis
Chairman, Health and Environment Subcommittee
House Commerce Committee

MB:rjm